

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Steven Curtis Zicker *et al.*

Examiner: Z. Vakili

Serial No.: 09/978,127

Art Unit: 1614

Filing Date: October 16, 2001

Confirmation No.: 3786

For: COMPOSITION AND METHOD

Attorney Docket No.: 6493-02-HL

**DECLARATION UNDER 37 C.F.R. § 1.131 OF
DRS. STEVEN C. ZICKER & KAREN J. WEDEKIND**

1. We are each co-inventors of pending Claims 39 and ~~44~~-47 of the above-captioned case.

2. We are aware that art has been cited against the claims by the Examiner in a non-final rejection dated, June 24, 2008.

3. We have been told that the earliest effective date of the Harper publication WO 00/44375 is January 31, 2000. We also understand the earliest effective date of the Hamilton patent U.S. Patent No. 6,335,361 is November 3, 1999, based on priority of Provisional Application No. 60/163,352 filed that date.

4. As demonstrated in the attachments, the invention that is the subject matter of Claims 39 and ~~44~~-47 was made on a date earlier than November 3, 1999. First, we demonstrate that a dog food containing four antioxidants (Vitamin E, Vitamin C, alpha-lipoic acid, and L-carnitine) was conceived and formulated before November 3, 1999. Then we show that the idea to use the ~~4~~-antioxidant composition in the claimed method was also made earlier than that date.

Composition with four antioxidants

5. The three pages attached as Exhibit A, B, and C are production batch sheets, showing production of a dog food containing Vitamin E, Vitamin C (ascorbic acid), L-carnitine, and alpha lipoic acid.

6. The Exhibits give the recipe for Formula No. 166668 described under Formula Description as "NMSENIOR TEST + CARNIT/TAU." Exhibit A is a "Make Sheet for Grain Mix," Exhibit B is a "Make Sheet for Grain Premix," and Exhibit C is a "Make Sheet for Topical." They illustrate a request for the formulations to be produced in the Hills Experimental Food Laboratory (EFL).

7. The Make Sheet for Grain Mix (Exhibit A) relates that the composition makes up 94.65 % of the finished product. The composition of the Make Sheet for Grain Premix (Exhibit B) makes up 2.36% by weight of the final product. The composition on the Make Sheet for Topical (Exhibit C) makes up 5.35% by weight of the finished product. The numbers for the premix are a component of the grain mix, which totals 94.65%. Therefore the grain mix is grain (92.29%), grain premix (2.36%), and topical (5.35%) which totals 100%.

8. The date redacted following "printed by Steven Zicker" at the upper left of the Exhibits is earlier than November 3, 1999. The Exhibits demonstrate that the formulas were conceived on or before the redacted date. The date is further corroborated by the initials LH of the Plant Manager, shown in redacted form at the top right of Exhibit B. The redacted date next to the Plant Manager's initials is also earlier than November 3, 1999.

9. The Exhibits also contain redacted dates next to initials at the lower right. The initials belong to the technicians who made the product in the EFL and to the Plant Manager LH who also signed off.

10. We are confident of the dates on the attached Exhibits. At the time of the invention, experimental formulas were computed in Agridata, a commercially available software program that was in use at Hill's in 1999 and earlier. Experimental formulas were first stored in my own personal folder. If the formula was to be made into a physical product, the following steps were taken:

- (1) Save the formula as a production formula in Agridata.
- (2) Export the formula to the Test Information Management System (TIMS) proprietary software for assignment of a formula number.
- (3) Once the formula number was assigned, a batch sheet could be produced for the EFL to make the food.
- (4) The batch sheet would be checked by the Plant Manager and scheduled for production.
- (5) The product was produced in the EFL, bagged and samples saved for analysis.
- (6) Analytical information was reported and downloaded into the TIMS with the associated formula number and date of production of the food.

The Exhibits show a Formula number of 16668 was assigned by the Agridata System. The attached Make Sheets for the product were checked by the Plant Manager, as indicated by his initials LH in the upper right hand corner of the Grain Premix Make Sheet. The "print date" redacted next to the name Steven Zicker in the upper left hand corner of the Exhibits is a reliable indication that the compositions were conceived on or before that date.

11. The Make Sheet for Grain Premix (Exhibit B) indicates the percent by weight of the diet of the four antioxidants: Vitamin E, Vitamin C, carnitine, and alpha lipoic acid. The ingredient listing indicates that the diet contains 0.241 % of Vitamin E (50% by weight), 0.029% of Vitamin C (ascorbic add), 0.25% by weight of 10% L-carnitine, and 0.014% by weight of alpha lipoic acid. These percentages by weights translate to the following ppm values, taking into account the percent active of the respective ingredient

Component	Calc'd from Recipe	Measured in Finished Product
Vitamin E	1205 ppm	935 ppm
Vitamin C	290 ppm	210 ppm
carnitine	257 ppm	266 ppm
alpha lipoic acid	140 ppm	136 ppm

The middle column is the amount calculated from the make sheets. The right hand column gives the results of the analytical measurement made on the actual batch 16668. These values are on an as is basis prior to correction for water content of the food. In addition, processing losses may occur during the extrusion process so that final analyzed values will be different from computer projection from the formulation alone. The variations of the measured from the calculated values in the table are completely normal and are expected.

12. "Carnitine" appearing in the Make Sheets and in the table above is L-carnitine. We only use L-carnitine in animal formulations. D-carnitine is toxic and our specification sheets are for L-carnitine only. Any other reference to carnitine in our databases or analyses means we are talking about L-carnitine.

13. In addition to the above levels of antioxidants, the finished product based on the three Make Sheets is a complete diet for an adult dog. The nutrients as projected by the computer program are sufficient to support the claims for a maintenance food for dogs above 1 year of age as per AAFCO (Association of American Feed Control Officials) recommendations.

14. We conclude that, based on the three Make Sheets attached as Exhibit A, B, and C, an embodiment of a pet food falling within the scope of Claims 39 and 44-47 was made on a date earlier than the November 3, 1999 earliest effective date of the art cited against our claims.

Method of use of the composition

15. At the time the composition was made, we intended to use it in the claimed method of inhibiting the loss of learning ability or increasing the learning ability of an aged companion pet. We had thus fully conceived the invention of the claims, and all that remained was for our contract lab to carry out the testing at our instruction.

16. We carried out the animal experiments at the Lovelace Respiratory Research Institute in New Mexico (LRRI). Appendix D is a document we submitted to LRRI for approval of the project according to USDA regulations. Those regulations require that all facilities doing animal testing have an Institutional Animal Care and Use Committee (IACUC) which reviews the projects for conformance to safety, health and other concerns.

17. The date of Appendix D is earlier than November 3, 1999. This is reflected in several places in the document. On the first page in the box marked "For Office Use Only," the date received and the approval date as well as the proposal number are redacted. The date received and approval date are earlier than November 3, 1999. The

proposal number is redacted because it contains information about the fiscal year in which the proposal was made. The revision date of the Form on the bottom of pages 1-4 is redacted. The revision date is earlier than November 3, 1999. The last page of Appendix D contains a signature by Dr. David G. Burt of the LRRI. The redacted date next to his signature is earlier than November 3, 1999. Also on the last page, the review date and its corrections next to Dr. Burt's initials are redacted. Those dates are also earlier than November 3, 1999.

18. Turning to page 1 of Appendix D, it is seen that the title of the project is "The effects of Hill's antioxidant diet on the development of age-dependent cognitive dysfunction and neuropathology in canines." This shows that the purpose of the testing at LRRI was to feed a diet containing antioxidants to older pets to study cognitive dysfunction.

19. In question 2 on page 2 of Appendix D, the scientific goals of the LRRI project were stated in non-scientific terms. As seen there, the explanation of the project suggests that older dogs are to be fed diets high in antioxidants and the effect on the development of age-dependent dementia, loss of memory and learning skills are to be studied. These indications are the claimed methods of inhibiting the loss of learning ability or increasing the learning ability of an aging companion pet in need of such treatment.

20. As explained further in question 3 of Appendix D, dogs in an "antioxidant diet group" will receive a diet rich in antioxidants, such as Vitamin E, Vitamin C, etc.

21. Cognitive testing of the subject animals is also indicated on page 4 of Appendix D. As noted at the top of page 4, the IACUC Office is required to prepare a list of experimental procedures performed on animals during the project. It is noted under Other, that "Cognitive testing" will be carried out.

22. As part of our testing at LRRI we were required to issue yearly progress reports to different agencies, which provided partial support of which one was the United States Army. A yearly progress report for this entity was created before November 3, 1999 is attached as Appendix E. Appendix E is a printout of a Microsoft Word document print screen view of the draft report file for this funding entity. The properties window of the Microsoft Word document indicate that creation date and the last modified dates are both earlier than November 3, 1999. A copy of the metadata of the Microsoft Word file is attached as the last page of Appendix E, with appropriate redactions.

23. The introduction on page 1 of Appendix E, consistent with Appendix D, explains that the effect of antioxidants on age-dependent cognitive decline is to be studied in dogs. The introduction states, "a broad spectrum of antioxidants will be added for dietary enrichment."

24. Appendix E explains that the project at LRRI was a 3-year design. The document of Appendix E represents a progress report after the first year.

25. The entire progress report is included in Appendix E. However, attention is drawn to page 4, the second to the last paragraph, where it is reported that antioxidants were considered for inclusion in the diets. Such antioxidants include Vitamin C, Vitamin E acetate, beta-carotene, carnitine, and lipoic acid.

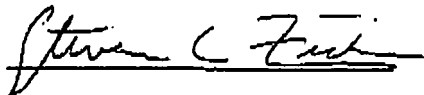
26. On page 5 bridging to page 6 of Appendix E, we explain that the "final intervention diet" was formulated to be the basal diet plus addition of other components. The other components included carrots, spinach, tomato pomace, grape pomace and citrus pulp. As particularly relevant to the claims, the final intervention diet was also formulated to contain Vitamin E, Ascorbic acid (Vitamin C), Selenium,

Carnitine, and Lipoic acid. Appendix E thus shows that we conceived the idea of feeding an intervention diet containing Vitamin E, Vitamin C, Carnitine and Lipoic acid to aged dogs in order to determine the effects of the antioxidants on age-dependent cognitive decline.


27. As discussed above, a diet containing the four antioxidants Vitamin E, Vitamin C, L-carnitine and lipoic acid was formulated on a date earlier than November 3, 1999. See the discussion above of Appendices A, B and C. Manufacture of the diet to be used in the LRR1 testing corroborates the conception of the idea given in Appendix E, that idea being to feed dogs a diet containing the four claimed antioxidants to inhibit the loss of learning ability or increase their learning ability.

28. We hereby declare under penalty of perjury that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: OCT 24, 2008


Steven C. Zicker, DVM, Ph.D.

Date: 10-22-08


Karen J. Wedekind, Ph.D.